

K024261

MAR 26 2003

## 510(k) Summary for the Dental Concepts Bite Plate

### 1. SPONSOR

Dental Concepts LLC  
650 From Road  
Paramus, NJ 07652

Contact Person: Michael Lesser, President  
Telephone: (201) 225-2151

Date Prepared: March 5, 2003

### 2. DEVICE NAME

Proprietary Name: None assigned at this time  
Common/Usual Name: Dental protector  
Classification Information:

Dental protectors have yet to be classified, but are proposed to be Class II devices, based on the recent classification of similar devices. Currently, predicate products are classified under the following classification name:

Name	Product Code	21 CFR Ref.	Panel
Jaw Repositioning Device	LQZ	872.5570	Dental

### 3. PREDICATE DEVICES

Dr. Hays Bite Guard, 510(k) No. K014079, cleared February 22, 2002

### 4. DEVICE DESCRIPTION

Dental Concepts' Bite Plate is a soft, comfortable, custom-fit protector intended to provide a barrier between the teeth for those patients who grind their teeth at night (bruxism). The product is shaped like a dental arch and is available in three sizes, but can be trimmed to fit more comfortably.

**5. INTENDED USE**

The Dental Concepts Bite Plate is indicated for protection against bruxism (nighttime teeth grinding) and jaw clenching during sleep, short-term pain relief from muscle spasm due to occlusal interference, and prevention of chronic tension and temporal mandibular joint (TMJ) syndrome that is caused by chronic jaw clenching of the posterior mandibular and maxillary teeth by the temporalis muscle.

**6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE**

The Bite Plate is composed of a soft, formable clear upper material, made of a thermoplastic resin and a base material composed of a thermoplastic resin. When the product is heated and then cooled briefly, the upper material can be molded to fit to the upper teeth. The Dr. Hays Bite Guard is composed of a single thermoplastic resin that, like the Bite Plate, can be custom fit to the mouth. The products have slightly different dimensions, but the Bite Plate can be trimmed to fit the mouth more comfortably.

A biocompatibility assessment was performed on the materials of the Bite Plate with satisfactory results.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 26 2003

Dental Concepts LLC  
C/O Mr. Michael Lesser  
Medical Device Consultant, Incorporated  
49 Plain Street  
North Attleboro, Massachusetts 02760

Re: K024261  
Trade/Device Name: Bite Plate  
Regulation Number: None  
Regulation Name: Dental Protector  
Regulatory Class: Unclassified  
Product Code: MQC  
Dated: March 5, 2003  
Received: March 6, 2003

Dear Mr. Lesser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

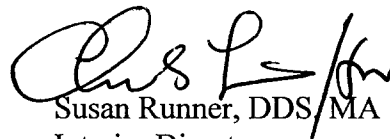
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan Runner", followed by a stylized flourish or initials.

Susan Runner, DDS/MA  
Interim Director

Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K024261

510(k) Number (if known): K024261

Device Name: Bite Plate

## Indications for Use:

The Dental Concepts Bite Plate is indicated for protection against bruxism (nighttime teeth grinding) and jaw clenching during sleep, short-term pain relief from muscle spasm due to occlusal interference, and prevention of chronic tension and temporal mandibular joint (TMJ) syndrome that is caused by chronic jaw clenching of the posterior mandibular and maxillary teeth by the temporalis muscle.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

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